NOV - 5 2003

510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part of the Premarket Notification in compliance with 21CFR. Part 807, Subpart E, Section 807.92

1) Submitter's name, address, telephone number, contact person

Curtis LeBleu, President
ConnexMD
8536 18th Ave NW
Seattle, WA 98117
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2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name:	Picture Archiving and Communications Systems Workstation
Proprietary Name:	EchoConnex Communicator
Classification Name:	Picture Archiving and Communications System, Class II

3) Device Description
The EchoConnex Communicator software provides a means of opening and displaying image files. The EchoConnex Communicator software provides a means of transferring medical image files using a DICOM network method from the acquisition devices to the Connex Acquisition Server. The Connex Acquisition Server provides a means for transferring the acquired studies to the Connex Central Server using standard networking methods.

The EchoConnex Communicator software provides a means to retrieve and view image data located on one of the Connex server devices using a standard network connection. The EchoConnex Communicator software provides a means for querying and retrieving patient studies from a networked DICOM server device.

The EchoConnex Communicator software provides a means of creating AVI, BMP, TIFF and JPG graphic files from the image data displayed by the software. The EchoConnex Communicator software provides a means of quantifying the image data using standard measurement tools.

4) Performance Standards
No performance standards for PACS systems or components have been issued under the authority of Section 514. The EchoConnex Communicator software has been designed to comply with the following voluntary standards:

ISO Joint Photographic Experts Group (JPEG) Image Compression Standard
DICOM Standard 3.0

5) General Safety and Effectiveness Concerns
The device labeling contains operating instructions for the safe and effective use of the EchoConnex Communicator software.

6) Substantially Equivalent Devices
Connex MD believes that the capabilities of the EchoConnex Communicator software makes it substantially equivalent to other image display products commercially available, specifically the CardioNow Cardiology Wide Area Network Archive and Retrieval System.

7) Software
Software development for the EchoConnex Communicator software follows documented processes for software design, verification and validation testing. A risk assessment has been completed to identify potential design hazards that could cause an error or injury based on the use of the software. Appropriate steps have been taken to control all identified risks for this type of image display and communication product.

8) Conclusions
The EchoConnex Communicator software is designed and manufactured to meet United States and international standards for the display and transmission of images acquired on medical imaging devices. The system is designed to incorporate components common to all image viewing systems for the display, manipulation and image transmission within a clinical setting. The EchoConnex Communicator software incorporates features of predicate devices cleared through premarket notification and no new issues of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2003

Mr. Curtis LeBleu
President
ConnexMD, Inc.
8536 18th Ave. NW
SEATTLE WA 98117

Re: K033093
Trade/Device Name: EchoConnex Communicator
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: September 26, 2003
Received: September 29, 2003

Dear Mr. LeBleu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Appendix B

Indication for Use Form

510K Number (if known) K033093

Device Name: EchoConnex Communicator Software

Indications for Use:

The EchoConnex Communicator System is a Windows 2000/Windows XP software application package. It is designed to view, quantify, transfer and store image data acquired on medical imaging devices.

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033093

Yes, Prescription Device ✓